UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/092,264	03/06/2002	Ambrose Cheung	DC-0187	9270

7590 10/04/2004

KATHLEEN A. TYRRELL, ESQ
LICATA & TYRRELL P.C.
66 E. MAIN STREET
MARLTON, NJ 08053

EXAMINER	
PATTERSON, CHARLES L JR	
ART UNIT	PAPER NUMBER
1652	

DATE MAILED: 10/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/092,264	CHEUNG, AMBROSE	
	Examiner	Art Unit	
	Charles L. Patterson, Jr.	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 August 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,8-10,13-21,23 and 25* is/are pending in the application.

4a) Of the above claim(s) *5-7,11,12,22 and 24* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,8-10,13-21,23 and 25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *06 March 2002* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Applicant's election with traverse of Group I, claims 1-4, 8-10, 23 and 25 in the reply filed on 7/28/04 is acknowledged. The traversal is on the ground(s) that there would not be a serious burden upon the examiner to examine Groups I and III. This argument is found persuasive and therefore Group III will be examined. Claims 1-4, 8-10, 23 and 25 and claims 13-21 limited to a method comprising identifying agents which inhibit expression of the nucleic acid of Group I will be examined.

The requirement is still deemed proper and is therefore made FINAL.

Claims 5-7, 11-12, 22, 24 and claims 13-21 not limited to a method comprising identifying agents which inhibit expression of the nucleic acid of Group I are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 7/28/04.

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 1-4, 8-10, 13-21, 23 and 25 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-4, 8-10, 13-21, 23 and 25 of copending Application No. 10/469,477. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 19 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 8 and 9 of copending Application No. 10/290,142. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of 10/290,142 are drawn to "[a] pharmaceutical composition...comprising...either an agent which regulates the expression or activity of a polypeptide encoded by SEQ ID NO:1" while the claim of this application is drawn to "[a] pharmaceutical composition...comprising...either an agent which inhibits the expression of a nucleic acid of claim 1 or an agent which inhibits the activity of a polypeptide encoded thereby". Claim 1 of is drawn to "[a] nucleic acid sequence which regulates expression of polypeptides involved in autolysis processes in bacteria" but the only embodiment of this taught in the specification is SEQ ID NO:1. Therefore the instant claims are claiming obvious variations of each other.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

The disclosure is objected to because of the following informalities:

On page 3, lines 11-12, the recitation of "Awhich…processes@" is not understood. Perhaps the phrase should be ""which…processes"".

Appropriate correction is required.

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-4 are rejected under 35 U.S.C. 101 because they are non-statutory. Claims in U.S. patent practice must have some indication of the "hand of man". Adding "isolated" or some similar recitation to the instant claims would overcome this rejection.

Claims 13, 16, 19, 23 and 25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 13, 16 and 19 are confusing in that they recite passages drawn to Group IV which was not elected for prosecution.

Claim 23 is confusing and indefinite in that it claims "[a] kit for identifying the presence of the RAT gene comprising a means for analyzing a biological sample for the presence of the RAT gene". This is the same as claiming a kit to detect A comprising a means to assay for A". The "means" is not identified in the claim and it would always be obvious to detect A by assaying for A. The claim is also indefinite in the recitation of "the RAT mutant gene" in line 2. There is no antecedent basis for this term earlier in the claim.

Claim 25 is confusing and indefinite for a similar reason as given for claim 23 *supra*. The claim is drawn to detecting a "RAT mutant gene" by as-

saying for "the RAT mutant gene". The claim is also indefinite in the recitation of "the RAT mutant gene" in line 2. There is no antecedent basis for this term earlier in the claim.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 13-21 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention and in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. This is a combination written description and enablement rejection.

The instant specification does not teach that even one agent that inhibits growth and infectivity, or that inhibits the expression of the nucleic acid of claim 1 has been made or found. Therefore one of ordinary skill in the art would not know how to make and/or use the invention of the instant claims and furthermore that artisan would not have at least a reasonable assurance that applicant had possession of the invention at the time of filing.

Claims 1-3, 8-10, 13-21, 23 and 25 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for SEQ ID NO: 1 or 3 from *Staphylococcus aureus*, does not reasonably provide enablement

for claims of the indicated scope. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The instant specification teaches that the RAT gene and a mutant gene (SEQ ID NO:1 and 3) are isolated from *Staphylococcus aureus*. It does not teach that any other gene that regulates expression of polypeptides involved in autolytic processes or that any other Rat gene has been isolated from any other source. Therefore the instant specification does not teach one of ordinary skill in the art to obtain nucleic acids of the scope of the instant claims.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-3 are rejected under 35 U.S.C. 102(a or b) as being anticipated by either of Brunskill, et al. (U), Fujimoto, et al. (V), Groicher, et al. (W), Brunskill, et al. (AA), Fournier, et al. (AC), Pinho, et al. (AH) and Ramadurai, et al. (AI). Brunskill, et al. (U) teach that a mutant of the *lytS* gene of *Staphylococcus aureus* "exhibited increased sutolysis" (abstract). Fujimoto, et al. teach that "mutations within the *Staphylococcus aureus* virulence factor regulatory gene, *agr* and *sar*, affect autolysis" (abstract). Groicher, et al. teach in the abstract that "the *Staphylococcus aureus* LctSR… affects murein hydrolase activity and autolysis…[and that a] *lrgAB* mutation enhanced penicillin-induced killing of cells…[and that] the data generated by this study suggest that penicillin-induced killing of *S. aureus* involves a novel regulator of murein hydrolase activity". Brunskill, et al. (AA) teach in the abstract that in *Staphylococcus aureus* "*lrgA* encodes a murein hydrolase supporter…while *lrgB* may encode a protein having murein hydrolase activity". Fournier, et al. teach in the abstract that "the *arlS* mutant [from *Staphylococcus aureus*] exhibited increased autolysis". Pinho, et al. teach in the abstract that "[i]nactivation of *pbpC* [from *Staphylococcus aureus*]…caused a small but significant decrease in the rates of autolysis". Ramadurai, et al. teach in the abstract that "[a] gene encoding an autolytic activity was identified in an autolysis-deficient mutant (Lyt^-) of *Staphylococcus aureus*. On page 8, lines 15-16 of the instant specification it is stated that "[e]xamples of autolytic enzymes include glucosamidase, muramidase, amidase, and endopeptidase". Therefore the instant references teach a nucleic acid from *Staphylococcus aureus* that regulates the expression of polypeptides involved in autolytic processes in bacteria, as required by the instant claims.

Claims 1-3, 8-10 and 13-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brunskill, et al. (U), Fujimoto, et al. (V), Groicher, et al. (W), Brunskill, et al. (AA), Fournier, et al. (AC), Pinho, et al. (AH) and Ramadurai, et al. (AI). The instant references have been characterized *supra*. It would have been obvious to put the gene of the instant references into a transposon, vector of host cell using widely known methods. The motivation would have been to further study the gene and/or to produce more of the gene or polypeptide encoded by it. The methods of claims 13-21 would have been obvious in view of the instant references in that they teach genes that are involved in autolysis and therefore the inhibition of infectivity of bacteria by using agents that inhibit the expression of the genes of the instant references would have been obvious.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charles L. Patterson, Jr., PhD, whose telephone number is 571-272-0936. The examiner can normally be reached on Monday - Friday from 7:30 to 4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, can be reached on 571-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the

Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Charles L. Patterson, Jr.
Primary Examiner
Art Unit 1652

Patterson
September 24, 2004